



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-0573]

Request for Nominations for Voting Members on a Public Advisory Committee; Blood Products Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for voting members to serve on the Blood Products Advisory Committee (the Committee) in the Center for Biologics Evaluation and Research. Nominations will be accepted for upcoming vacancies effective with this notice. FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore encourages nominations of appropriately qualified candidates from these groups.

DATES: Nominations received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] will be given first consideration for membership on the Blood Products Advisory Committee. Nominations received after [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] will be considered for nomination to the committee as later vacancies occur.

ADDRESSES: All nominations for membership should be sent electronically by logging into the FDA Advisory Nomination Portal:

<https://www.accessdata.fda.gov/scripts/factrsportal/factrs/index.cfm>. Information about

becoming a member on an FDA advisory committee can also be obtained by visiting FDA's website at <https://www.fda.gov/advisory-committees>.

FOR FURTHER INFORMATION CONTACT: Christina Vert, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6268, Silver Spring, MD 20993-0002, 240-402-8054, Fax: 301-595-1309, email: Christina.Vert@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

FDA is requesting nominations for voting members to fill upcoming vacancies on the Blood Products Advisory Committee.

I. General Description of the Committee Duties

The Committee reviews and evaluates available data concerning the safety, effectiveness, and appropriate use of blood, products derived from blood and serum or biotechnology which are intended for use in the diagnosis, prevention, or treatment of human diseases, and, as required, any other product for which FDA has regulatory responsibility, and advises the Commissioner of Food and Drugs (the Commissioner) of its findings regarding screening and testing (to determine eligibility) of donors and labeling of the products, on clinical and laboratory studies involving such products, on the affirmation or revocation of biological products licenses, and on the quality and relevance of FDA's research program which provides the scientific support for regulating these agents. The Committee will function at times as a medical device panel under the Federal Food, Drug, and Cosmetic Act Medical Device Amendments of 1976. As such, the Committee recommends classification of devices subject to its review into regulatory categories; recommends the assignment of a priority for the application of regulatory requirements for devices classified in the standards or premarket approval category; advises on formulation of

product development protocols and reviews premarket approval applications for those devices to recommend changes in classification as appropriate; recommends exemption of certain devices from the application of portions of the Act; advises on the necessity to ban a device; and responds to requests from the Agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices.

II. Criteria for Voting Members

The Committee consists of a core of 17 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of clinical and administrative medicine, hematology, immunology, blood banking, surgery, internal medicine, biochemistry, engineering, biological and physical sciences, biotechnology, computer technology, statistics, epidemiology, sociology/ethics, and other related professions. Almost all non-Federal members of this committee serve as Special Government Employees. Members will be invited to serve for terms of up to 4 years.

III. Nomination Procedures

Any interested person may nominate one or more qualified persons for membership on the advisory committee. Self-nominations are also accepted. Nominations must include a current, complete résumé or curriculum vitae for each nominee, including current business address, telephone number, and email address if available and a signed copy of the Acknowledgement and Consent form available at the FDA Advisory Nomination Portal (see ADDRESSES). Nominations must specify the advisory committee for which the nominee is recommended. Nominations must also acknowledge that the nominee is aware of the nomination unless self-nominated. FDA will ask potential candidates to provide detailed information

concerning such matters related to financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflicts of interest.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: August 14, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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